K000716

Section 1 D: SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE ACCESS® CK-MB ASSAY

1. 0 General Information

Device Generic Name:	Enzyme Immunoassay, CK-MB
Device Trade Name:	Access® CK-MB Reagents for use on the Access® Immunoassay Analyzers
Device Class:	Class II
Applicant's Name and Address:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Date:	March 1, 2000

2.0 Legally Marketed Device

The modified Access® CK-MB Immunoassay claims substantial equivalence to the Access® CK-MB Immunoassay currently in commercial distribution.

FDA 510(k) Number: K994439

3.0 Device Description

The Access® CK-MB reagents consist of reagent packs, calibrators, controls, diluent, substrate, and wash buffer.

- The Access® CK-MB Reagent Packs contain specific reagents for the *in vitro* diagnostic measurement of CK-MB: mouse monoclonal anti-human CK-MB antibody-alkaline phosphatase conjugate in buffer, paramagnetic particles coated with mouse monoclonal anti-human CK-BB antibody in buffer and mouse IgG in buffer.

- The Access® CK-MB Calibrator Set contains multi-point calibrator sera for use with the Access CK-MB assay. Each vial contains concentrations of recombinant human CK-MB of approximately 0, 3, 10, 30, 100, and 300 ng/ml, respectively, in a buffered bovine serum albumin (BSA) matrix with preservatives.

- The Access® CK-MB QC Control Set consists of multi-point controls for use with the Access CK-MB assay. Each vial contains recombinant human CK-MB at concentrations of approximately 4, 9, and 80 ng/ml, respectively, in a buffered bovine serum albumin (BSA) matrix with preservatives.

- The Access® CK-MB Diluent is used to dilute patient samples with CK-MB concentrations > the S5 calibrator. The diluent consists of a bovine serum albumin (BSA) matrix with preservatives.

- The Access® Substrate, Lumi-Phos* 530, is a dioxetane-based chemiluminescent substrate. After addition of alkaline phosphatase, the substrate is dephosphorylated resulting in the spontaneous release of light. This light is measured by a luminometer.

- The Access® Wash Buffer consists of Tris buffered saline containing surfactant and preservatives. The wash buffer is used for the following: 1) clean the pipetting probe tip in the Access Immunoassay Analyzers, 2) wash paramagnetic particles to remove unbound analyte and excess reagents in each reaction, and 3) as a diluent in designated assays.

4.0 Principles of the Procedure

The Access CK-MB assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-human CK-MB antibody-alkaline phosphatase conjugate and paramagnetic particles coated with mouse monoclonal anti-human CK-BB antibody. CK-MB in human serum or plasma binds to the immobilized anti-CK-BB on the solid phase by the sub-unit B epitopes (common to CK-BB and CK-MB isoforms), while the mouse anti-CK-MB conjugate reacts specifically with serum or plasma CK-MB (no reaction with CK-MM or CK-BB isoforms). After the incubation, separation in a magnetic field and washing removes material not bound to the solid phase. A chemiluminescent substrate, Lumi-Phos* 530, is added to the reaction vessel and light generated by the reaction is measured with a luminometer. The light production is proportional to the amount of CK-MB in the sample. The amount of analyte is determined by means of a stored, multi-point calibration curve.

The precise relationship between the known concentration of CK-MB in the calibrators and the light generated by the chemiluminescent reaction establishes a calibration curve. The measured light production for a given sample is transformed to the amount of analyte contained in an unknown sample by means of the nonlinear calibration curve.

5.0 Indications for Use

The Access® CK-MB assay is a paramagnetic-particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum or plasma, using the Access Immunoassay Systems. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction.

6.0 Description of the Modification to the Legally Marketed Device

The Access® CK-MB assay has been modified to change the calibrators and quality control (QC) materials from a lyophililized state to a liquid state. This change will improve the ease of use since the materials are now provided ready to use. The QC materials have been changed from a single level to tri-levels.

Additionally, the antigen has been changed from human CK-MB to recombinant human CK-MB. The recombinant antigen is an internationally recognized preparation process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

Ms. Angela Byland, B.S. M.T.
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K000716
Trade Name: Access® CK-MB Assay for use in the Access® Immunoassay Analyzer
Regulatory Class: II
Product Code: JHX
Dated: March 1, 2000
Received: March 3, 2000

Dear Ms. Byland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 1 C: **INDICATIONS FOR USE STATEMENT**

510(k) Number: K000716

Device Name: Access® CK-MB Assay for use on the Access® Immunoassay Analyzer

Indications for Use:

The Access® CK-MB assay is a paramagnetic-particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum or plasma, using the Access Immunoassay Systems. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000716

Prescription Use ✓ OR Over-The Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)